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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,809	02/08/2002	Marilyn Anne Anderson	18-01	3677
23713	7590	03/11/2004	EXAMINER	
GREENLEE WINNER AND SULLIVAN P C			KUBELIK, ANNE R	
5370 MANHATTAN CIRCLE			ART UNIT	
SUITE 201			PAPER NUMBER	
BOULDER, CO 80303			1638	

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,809

Applicant(s)

ANDERSON ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-78 is/are pending in the application.
- 4a) Of the above claim(s) 63-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-62 and 67-75 is/are rejected.
- 7) ☒ Claim(s) 76-78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election with traverse of Group V, drawn to a nucleic acid encoding a protein of SEQ ID NOs:8, 14, 16 or 18, methods of using it, and cells transformed with it, in the response filed 19 December 2003 is acknowledged. This group corresponds to the instant claims 55-62 and 66-78. The traversal is on the ground(s) that the protein is technically linked to the nucleic acid because it is encoded by it, and the claimed plants and methods share this feature, a nucleic acid or protein having a protective activity against a plant pest.

This is not found persuasive. Applicant is reminded that a protein is not technically linked to the polynucleotide that encodes it and that the polynucleotide and the polypeptide are not linked because the polynucleotide encodes the polypeptide. The polypeptide is not directly made from the DNA molecule that encodes it. While the nucleic acid sequence may provide researchers the amino acid sequence of the initially-translated protein, it does not allow them to accurately predict properties of the protein like K_m , temperature maximum, or even molecular weight of the processed protein. Additionally, the protein can be isolated from the natural source and characterized in detail without knowledge of the DNA that encodes it, and in fact, many proteins were isolated years before DNA cloning and sequencing were possible. Thus, the protein is **not** technically linked to nucleic acid that encodes it, and vice versa.

The requirement is still deemed proper and is therefore made FINAL.

Claims 63-66 are withdrawn from consideration as being drawn to a non-elected invention. Claims 55-62 and 67-78 are examined to the extent they read on a nucleic acid encoding SEQ ID NOs:8, 14, 16 or 18.

2. The abstract is not descriptive of the instant invention, which is a nucleic acid from *Nicotiana glauca* that encodes a defensin, methods of using it to induce resistance of a plant to

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plant pests and plants thereby obtained. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

3. The title of the invention is not descriptive of the instant invention, as above. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.

4. The disclosure is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code. See pg 71, line 31. Applicant is required to delete the embedded hyperlinks and/or other forms of browser-executable code. See MPEP § 608.01.

5. New corrected drawings are required in this application because in Figure 1, some of the sequence is unreadable because of the presence of the black box, and in Figure 7, details cannot be made out. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

6. The oath or declaration is defective because non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Objections

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7. Claims 76-78 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 76 and the claims dependent upon it, claims 77-78, have not been further treated on the merits.

8. Claims 67-69 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The polypeptide of SEQ ID NO:8 would inherently have activity against an insect, a fungus and be derived from *Nicotiana glauca*. Thus, the nucleic acid of each of claims 67-69 fails to further limit the nucleic acid of parent claim 55.

9. Claims 55-62, 67-69, 72 and 75 are objected to because of the following informalities:

In claim 55, line 3, there is an improper article before “amino” and there should be a comma after “SEQ ID NO:8”.

In claims 56-58, 72 and 75, line 1, there should be a comma before “wherein”.

In claim 56, line 2, there is an improper article before “C-terminal”.

In claim 57, line 2, there is an improper article before “signal”.

In claim 58, line 2, there is an improper article before “amino”.

In claims 59-62, line 1, there should be a comma before “comprising”.

In claims 67-69, line 2, there should be a comma before “wherein”.

10. Claims 67-69, 71 and 74 are objected to for being dependent upon non-elected claims.

11. Claims 60-61 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the

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claims in independent form. The nucleic acids of claims 60-61, SEQ ID NOs:11 and 9, respectively, do not encode SEQ ID NO:8; thus, the claims fail to further limit parent claims 56 and 57, which encode a protein of SEQ ID NO:8.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 55-57, 60-61, 67-70 and 72-75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding SEQ ID NO:18, plant cells, plant parts and plants transformed with it and a method of using it to induce plant pest resistance in a plant, does not reasonably provide enablement for a method of using a nucleic acid encoding SEQ ID NO:8 to induce plant pest resistance in a plant, and plant cells, plant parts and plants thereby obtained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to nucleic acids encoding SEQ ID NO:8, plant cells, plant parts and plants transformed with it and a method of using it to induce plant pest resistance in a plant.

The instant specification, however, only provides guidance for cloning of NaPdf1 using PCR primers based on the sequence of tobacco flower specific thionin (examples 1-2), analysis of its gene expression (example 3), production of antibody to proprotein domains (example 4); extraction of the protein from floral buds (example 5); immunolocalization to flowers (example

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6), sequence determination to obtain the DNA (SEQ ID NO:17) and amino acid (SEQ ID NO:18) sequences and alignment with similar proteins (example 7); fungal growth inhibition assays on the protein (example 8) transformation of tobacco and cotton with the full-length DNA and testing of the insect resistance of the transformed plants (examples 9-12); and prophetic cloning of homologous sequences from other plants and transformation into plants (example 13).

The instant specification fails to provide guidance for a method of using a nucleic acid encoding only SEQ ID NO:8 to induce plant pest resistance in a plant, and plant cells, plant parts and plants thereby obtained.

The defensin the protein of SEQ ID NO:18 is most similar to is the thionin taught by Gu et al (1992, Mol. Gen. Genet. 234:89-96; see sequence search results and see also Figure 9 of the instant specification); thus, SEQ ID NO:18 is most probably also a thionin. Thionins inhibit protein synthesis (Mendez et al, 1990, Eur. J. BioChem. 194:533-539; see Figure 4-6). Thus, production of the mature thionin in the cytoplasm of the plant cell would most likely be toxic to the plant.

In plants thionins are present in an organelle, the vacuole, which separates the mature protein from the translational machinery. Transport to the vacuole requires a N-terminal signal sequence for direction to the endoplasmic reticulum. The C-terminal peptide of a thionin precursor is required for vacuolar targeting (Romero et al 1997, Eur. J. Biochem. 243:202-208; pg 207, left column, paragraph 1). Plants transformed with a nucleic acid encoding only the mature peptide would express the protein only in the cytoplasm.

SEQ ID NO:8 is the mature peptide made from SEQ ID NO:18, in which the N-terminal sequence and the C-terminal sequence have been removed. Given the toxicity of the mature peptide to plant function, expression of only SEQ ID NO:8 would be toxic to the plant.

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Applicant only expressed a nucleic acid encoding SEQ ID NO:18 in a plant, and does not teach how to overcome the toxicity of expressing a nucleic acid encoding only SEQ ID NO:8 in a plant.

Furthermore, claims 60-61 are drawn to nucleic acids of SEQ ID NOs:11 and 9, which encode the C-terminal and N-terminal sequences, respectively, and which do not encode SEQ ID NO:8. Parent claims 55-57 are drawn to nucleic acid encoding SEQ ID NO:8. The specification does not teach how to use a sequence that does not encode SEQ ID NO:8 to produce a protein of SEQ ID NO:8.

Given the claim breath, state of the art, and lack of guidance as discussed above, the instant invention is not enabled throughout the full scope of the claims.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 57-58, 62, 73 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

In claims 57-58 it is unclear where SEQ ID NOs:12 and 10 are located relative to SEQ ID NO:8.

In claim 73 it is unclear if the progeny comprise the nucleic acid.

Claim 75 is indefinite in its recitation of “connective tissue of another”. It is unclear what is intended here - what tissue is the connective tissue of a plant and what is the connective tissue of another?

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16. Claims 55-62 and 66-75 are free of the prior art, given the failure of the prior art to teach or suggest an isolated nucleic acid encoding a protein comprising SEQ ID NO:8. The closest prior art is Gu et al (1992, Mol. Gen. Genet. 234:89-96), who teach a nucleic acid that encodes a protein with 95.2% identity to SEQ ID NO:18 and higher identity to SEQ ID NOs:8, 14 and 16. The nucleic acid has 95.7% identity to SEQ ID NO:17.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
March 9, 2004



**ANNE KUBELIK
PATENT EXAMINER**